## DETAILED ACTION

### *Continued Examination Under 37 CFR 1.114*

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on October 6, 2009 has been entered.

Claims 1-102, 15-106, and 109 have been cancelled. Accordingly, claims 103-104, 107-108, and 110-111 are pending in the instant application.

### *Claim Rejections - 35 USC § 112*

1. The rejection of claims 103-104, and 107-108 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods of inhibiting programmed cell death in plant eukaryotes with SEQ ID NO: 2, does not reasonably provide enablement for inhibiting programmed cell death in all eukaryotes with any bacterial effector protein is withdrawn in view of Applicants amendment.

### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. The rejection of claims 103, 107 and 110 under 35 U.S.C. 102(b) as being anticipated by Nimchuk et al is withdrawn in view of Applicants amendment.

The following new grounds of rejection are applied to the amended claims:

***Claim Rejections - 35 USC § 112***

3. Claims 103, 107 and 110-111 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, this is a written description rejection.

Claims 103, 107 and 110-111 recite a method of inhibiting programmed cell death in a plant or yeast eukaryote, said method comprising administering…"the amino acid sequence spanning ***a*** C-terminus ***of*** SEQ ID NO: 2." (Emphasis added).

The specification and claims do not indicate what distinguishing attributes are shared by the members of the genus. Thus, the scope of the claims includes numerous structural variants, and the genus is highly variant because a significant number of structural differences between genus members is permitted. Since the disclosure fails

to describe the common attributes or characteristics that identify members of the genus, and because the genus is highly variant, "spanning a C-terminus of SEQ ID NO: 2" alone are insufficient to describe the genus. One of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe the genus. Thus, applicant was not in possession of the claimed genus.

The specification and claims do not place any limit on the number of amino acid deletions or subsequent insertions that may be made to the C-terminus of SEQ ID NO: 2. Applicants specification (paragraphs 50-51) clearly contemplate "fragments" of the bacterial effector protein, however the fragment can go all the way down to a single amino acid within the C-terminus of SEQ ID NO: 2. This in combination with the transitional phrase of "comprising" allows for the generation of virtually every protein known to man. Applicants description of SEQ ID NO: 2 is simply not commensurate in scope with a genus claim encompassing every protein on earth.

Adequate written description requires more than a mere statement that it is part of the invention and a reference to a potential method of isolating it. The protein itself is required. See *Fiers v. Revel*, 25 USPQ 2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. V. Chugai Pharmaceutical Co. Lts.*, 18 USPQ2d 1016.

*Vas-Cath Inc. V. Mahurkar*, 19 USPQ2d 111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed." The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented

what is claimed."

Applicant is reminded that Vas-Cath make clear that the written description provision of 35 USC 112 is severable from its enablement provision.

Furthermore, in *The Regents of the University of California v. Eli Lilly* (43 USPQ2d 1398-1412), the court held that a generic statement which defines a genus by only their functional activity does not provide an adequate written description of the genus. The court indicated that while Applicants are not required to disclose every species encompassed by a genus, the description of a genus is achieved by the recitation of a representative number of DNA molecules, usually defined by a nucleotide sequence, falling within the scope of the claimed genus. At section B(1), the court states that "An adequate written description of a DNA... requires a precise definition, such as by structure, formula, chemical name, or physical properties, not a mere wish or plan for obtaining the claimed chemical invention."

Applicants are directed to the Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, 1 "Written Description" Requirement, the guidelines can be found at the following link on the USPTO Internet in "Patents Guidance" Specifically, Example 9, which is analogous to the recitation of a fragment of a protein/variant.

<http://www.uspto.gov/web/patents/guides.htm>

### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 103, 107 and 110-111 are rejected under 35 U.S.C. 102(b) as being anticipated by Briggs et al.

The claims are directed to a method of inhibiting programmed cell death in a plant or yeast eukaryote, said method comprising administering…"the amino acid sequence spanning a C-terminus of SEQ ID NO: 2."

Briggs et al (US Patent Number 6,211,437) disclose of administering bacterial effector proteins to plant cells which inhibited programmed cell death. (See abstract, examples and claims). Briggs et al further disclose of the sequences of these proteins. (See sequence listing).

Given that the proteins disclosed by Briggs et al share some of the same "C-terminus" amino acids of SEQ ID NO: 2 of the instant invention, the disclosure of Briggs et al is deemed to anticipate each and every limitation of the instantly filed claims.

### *Double Patenting*

5. Applicant is advised that should claim 110 be found allowable, claim 111 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two

claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

6. Claims 104 and 108 are objected to for depending upon a rejected base claim, but would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 1st paragraph, and 35 U.S.C. 102(b) (i.e., deletion of the phrase "the amino acid sequence spanning a C-terminus of SEQ ID NO: 2), set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Navarro whose telephone number is (571) 272-0861.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Mondesi can be reached on (571) 272-0956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Mark Navarro/
Primary Examiner, Art Unit 1645
January 27, 2010